## CENTER FOR DRUG EVALUATION AND RESEARCH

**APPLICATION NUMBER:** 

50-720/S-001

**CHEMISTRY REVIEW(S)** 

CHI	EMIST'S REVIEW	1. ORGANIZATION DAIDP (HFD-520)	2. NDA NUMBER 50 - 720
3.	NAME & ADDRESS OF		4. AF NUMBER
	SmithKline Beecham	n Pharmaceuticals	5. SUPPLEMENT(s)
		Le Road, PO Box 5089	NUMBER (s) DATE (s)
	Collegeville, PA 1	19426-0989	SCM-001 3/27/96
6.	NAME OF DRUG	7. NONPROPRIETARY N	
	Augmentin	Amoxicillin/Clav	lanate Potassium
в.	SUPPLEMENT (s) PROV		NDMENTS AND OTHER
	SCM-001: For re-instating the (REPORTS, etc.) DATES none		
		facility for	<b>5</b>
	the the	ractify for	
10.	PHARMACOLOGICAL	11. HOW DISPENSED 1	12. RELATED
	CATEGORY		IND/NDA/DMF(s)
	Antimicrobial	XXX	
		RX OTC	
L3.	DOSAGE FORM(s)	14. POTENCY (ies)	
	Tablet		mg/Clavulanate
		potassium 125mg	J/Tablet
(25 -3,	3-dimethyl-7-oxo-4	-2-Amino-2-(p-hydroxy-thia-1-azabicyclo[3.	
(25 -3, car m.w CAS	5,5R,6R)-6-[(R)-(-) 3-dimethyl-7-oxo-4 boxylic acid trihy 7. 419.46 5 Registry No. 6133	-2-Amino-2-(p-hydroxy -thia-1-azabicyclo[3. drate 6-70-7 C <sub>8</sub> H <sub>8</sub> KNO5	yphenyl)acetamido] 2.0]-heptane-2-
(25 -3, car m.w CAS	5,5R,6R)-6-[(R)-(-) 3-dimethyl-7-oxo-4 boxylic acid trihy 4. 419.46 5 Registry No. 6133 4 vulanate potassium 5 cassium (Z)-(2R,5R)	-2-Amino-2-(p-hydroxy -thia-1-azabicyclo[3. drate 6-70-7 C <sub>8</sub> H <sub>8</sub> KNO5 -3-(2-hydroxyethylide	yphenyl)acetamido] 2.0]-heptane-2-
(25 -3, car m.w CAS Cla	S,5R,6R)-6-[(R)-(-) 3-dimethyl-7-oxo-4 boxylic acid trihy 7. 419.46 5 Registry No. 6133 4 vulanate potassium 5 assium (Z)-(2R,5R) 6 bicyclo[3.2.0]-hep	-2-Amino-2-(p-hydroxy -thia-1-azabicyclo[3. drate 6-70-7 C <sub>8</sub> H <sub>8</sub> KNO5 -3-(2-hydroxyethylide tane-2-carboxylate	<pre>rphenyl) acetamido] 2.0]-heptane-2- ene)-7-oxo-4-oxa-1-</pre>
(25 -3, car m.w CAS Cla Pot aza	S,5R,6R)-6-[(R)-(-) 3-dimethyl-7-oxo-4 boxylic acid trihy 7. 419.46 5 Registry No. 6133 4 vulanate potassium (assium (Z)-(2R,5R) (bicyclo[3.2.0]-hep 7. 237.25	-2-Amino-2-(p-hydroxy -thia-1-azabicyclo[3. drate 6-70-7 C <sub>8</sub> H <sub>8</sub> KNO5 -3-(2-hydroxyethylide tane-2-carboxylate 16. RECO	<pre>Phenyl) acetamido] 2.0] - heptane - 2 - ene) - 7 - oxo - 4 - oxa - 1 - PRDS AND REPORTS</pre>
(25 -3, car m.w CAS Cla Pot aza	S,5R,6R)-6-[(R)-(-) 3-dimethyl-7-oxo-4 boxylic acid trihy 7. 419.46 5 Registry No. 6133 4 vulanate potassium 5 assium (Z)-(2R,5R) 6 bicyclo[3.2.0]-hep	-2-Amino-2-(p-hydroxy -thia-1-azabicyclo[3. drate 6-70-7 C <sub>8</sub> H <sub>8</sub> KNO5 -3-(2-hydroxyethylide tane-2-carboxylate 16. RECO	yphenyl)acetamido] 2.0]-heptane-2- ene)-7-oxo-4-oxa-1- ORDS AND REPORTS Yes No
(28 -3, car m.w CAS Cla Pot a.w CAS	5,5R,6R)-6-[(R)-(-) 3-dimethyl-7-oxo-4 boxylic acid trihy 7. 419.46 6 Registry No. 6133 6 Registry No. 6133 6 Registry No. 6133 6 Registry No. 6137 6 Registry No. 6117	-2-Amino-2-(p-hydroxy -thia-1-azabicyclo[3. drate 6-70-7 C <sub>8</sub> H <sub>8</sub> KNO5 -3-(2-hydroxyethylide tane-2-carboxylate 16. RECO	yphenyl)acetamido] 2.0]-heptane-2- ene)-7-oxo-4-oxa-1- ORDS AND REPORTS Yes No
(25 -3, car .ww. CAS Cla Pot aza .w. CAS	S,5R,6R)-6-[(R)-(-) 3-dimethyl-7-oxo-4 boxylic acid trihy 4. 419.46 5 Registry No. 6133 cvulanate potassium cassium (Z)-(2R,5R) bicyclo[3.2.0]-hep 4. 237.25 6 Registry No. 6117  COMMENTS This drug is the	-2-Amino-2-(p-hydroxy -thia-1-azabicyclo[3. drate 6-70-7 C <sub>8</sub> H <sub>8</sub> KNO5 -3-(2-hydroxyethylide tane-2-carboxylate 16. RECO	phenyl)acetamido] 2.0]-heptane-2- ene)-7-oxo-4-oxa-1- ene)-RDS AND REPORTS Yes No lial monograph, USP
(25 -3, car .ww. CAS Cla Pot aza .w. CAS	S,5R,6R)-6-[(R)-(-) 3-dimethyl-7-oxo-4 boxylic acid trihy 419.46 Registry No. 6133 vulanate potassium cassium (Z)-(2R,5R) bicyclo[3.2.0]-hep 237.25 Registry No. 6117 COMMENTS This drug is the page 104. See ite	-2-Amino-2-(p-hydroxy-thia-1-azabicyclo[3.drate 6-70-7  C <sub>8</sub> H <sub>8</sub> KNO5 -3-(2-hydroxyethylide tane-2-carboxylate 16. RECO 7-45-5 CURRENT REVIEWED subject of a compend ms 20-34 for detailed	phenyl)acetamido] 2.0]-heptane-2- ene)-7-oxo-4-oxa-1- ene)-7-oxo-4-oxa-1- ene)-No ene)-No ene)-7-oxo-4-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa
(25 -3, car m.w CAS Cla Pot aza m.w CAS	S,5R,6R)-6-[(R)-(-) 3-dimethyl-7-oxo-4 boxylic acid trihy 419.46 Registry No. 6133 vulanate potassium cassium (Z)-(2R,5R) bicyclo[3.2.0]-hep 237.25 Registry No. 6117 COMMENTS This drug is the page 104. See ite	-2-Amino-2-(p-hydroxy-thia-1-azabicyclo[3.drate 6-70-7  C <sub>8</sub> H <sub>8</sub> KNO5 -3-(2-hydroxyethylidetane-2-carboxylate 16. RECO 7-45-5 CURRENT REVIEWED subject of a compendents 20-34 for detailed	phenyl)acetamido] 2.0]-heptane-2- ene)-7-oxo-4-oxa-1- ene)-7-oxo-4-oxa-1- ene)-No ene)-No ene)-7-oxo-4-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa
(25 -3, car m.w CAS Cla Pot aza m.w CAS	S,5R,6R)-6-[(R)-(-) 3-dimethyl-7-oxo-4 boxylic acid trihy 4. 419.46 5 Registry No. 6133 cvulanate potassium cassium (Z)-(2R,5R) bicyclo[3.2.0]-hep 7. 237.25 6 Registry No. 6117  COMMENTS This drug is the page 104. See ite  CONCLUSIONS AND Recommend approv  Orig: NDA 50-720	-2-Amino-2-(p-hydroxy-thia-1-azabicyclo[3.drate 6-70-7  C <sub>8</sub> H <sub>8</sub> KNO5 -3-(2-hydroxyethylide tane-2-carboxylate 16. RECO 7-45-5 CURRENT REVIEWED subject of a compend ms 20-34 for detailed RECOMMENDATIONS al letter to issue for	phenyl)acetamido] 2.0]-heptane-2- ene)-7-oxo-4-oxa-1- ene)-7-oxo-4-oxa-1- ene)-No ene)-No ene)-7-oxo-4-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1- ene)-7-oxa
(25 -3, car m.w CAS Cla Pot aza CAS 17.	S,5R,6R)-6-[(R)-(-) 3-dimethyl-7-oxo-4 boxylic acid trihy 4. 419.46 5 Registry No. 6133 cvulanate potassium cassium (Z)-(2R,5R) bicyclo[3.2.0]-hep 7. 237.25 6 Registry No. 6117  COMMENTS This drug is the page 104. See ite  CONCLUSIONS AND Recommend approv  Orig: NDA 50-720 HFD-520	-2-Amino-2-(p-hydroxy-thia-1-azabicyclo[3.drate 6-70-7  C <sub>8</sub> H <sub>8</sub> KNO5 -3-(2-hydroxyethylide tane-2-carboxylate 16. RECO 7-45-5 CURRENT REVIEWED subject of a compend ms 20-34 for detailed RECOMMENDATIONS al letter to issue for HFC-130/JAllen HFC-520/Roberts	phenyl)acetamido] 2.0]-heptane-2- ene)-7-oxo-4-oxa-1- ene)-7-oxo-4-oxa-1- ene)-No ene)-No ene)-7-oxo-4-oxa-1- ene)-7-oxa-1- en
(25 -3, car m.w CAS Cla Pot aza CAS 17.	S,5R,6R)-6-[(R)-(-) 3-dimethyl-7-oxo-4 boxylic acid trihy 4. 419.46 5 Registry No. 6133 cvulanate potassium cassium (Z)-(2R,5R) bicyclo[3.2.0]-hep 7. 237.25 6 Registry No. 6117  COMMENTS This drug is the page 104. See ite  CONCLUSIONS AND Recommend approv  Orig: NDA 50-720	-2-Amino-2-(p-hydroxy-thia-1-azabicyclo[3.drate 6-70-7  C <sub>8</sub> H <sub>8</sub> KNO5 -3-(2-hydroxyethylide tane-2-carboxylate 16. RECO 7-45-5 CURRENT REVIEWED subject of a compend ms 20-34 for detailed RECOMMENDATIONS al letter to issue for	phenyl)acetamido] 2.0]-heptane-2- ene)-7-oxo-4-oxa-1- ene)-7-oxa-1- ene)-7-oxa-1
(25 -3, car m.w CAS Cla Pot aza CAS 17.	comments This drug is the page 104. See ite  CONCLUSIONS AND Recommend approv  Orig: NDA 50-720 HFD-520/SPagay	-2-Amino-2-(p-hydroxy-thia-1-azabicyclo[3.drate 6-70-7  C <sub>8</sub> H <sub>8</sub> KNO5 -3-(2-hydroxyethylide tane-2-carboxylate  16. RECO 7-45-5  CURRENT REVIEWED subject of a compend ms 20-34 for detailed RECOMMENDATIONS al letter to issue for HFC-130/JAllen HFD-520/Roberts HFD-520/Cintron	phenyl)acetamido] 2.0]-heptane-2- ene)-7-oxo-4-oxa-1- ene)-7-oxo-4-oxa-1- ene)-No ene)-No ene)-7-oxo-4-oxa-1- ene)-7-oxa-1- en
(25, car with the control of the con	comments This drug is the page 104. See ite  CONCLUSIONS AND Recommend approv  Orig: NDA 50-720  HFD-520/Buko HFD-520/SPagay	-2-Amino-2-(p-hydroxy-thia-1-azabicyclo[3.drate  6-70-7  C <sub>8</sub> H <sub>8</sub> KNO5 -3-(2-hydroxyethylide tane-2-carboxylate 16. RECO 7-45-5 CURRENT REVIEWED subject of a compend ms 20-34 for detailed  RECOMMENDATIONS al letter to issue for HFC-130/JAllen HFD-520/Roberts HFD-520/Cintron HFD-520/SBRoy:R/D	phenyl)acetamido] 2.0]-heptane-2- ene)-7-oxo-4-oxa-1- ene)-7-oxo-4-oxa-1- ene)-No ene)-No ene)-7-oxo-4-oxa-1- ene)-7-oxa-1- en
(25 -3, -3, -car m.w CAS Clatar CAS 17. 18.	comments This drug is the page 104. See ite  CONCLUSIONS AND Recommend approv  Orig: NDA 50-720  HFD-520/Buko HFD-520/SPagay	-2-Amino-2-(p-hydroxy-thia-1-azabicyclo[3.drate  6-70-7  C <sub>8</sub> H <sub>8</sub> KNO5 -3-(2-hydroxyethylide tane-2-carboxylate 16. RECO 7-45-5 CURRENT REVIEWED subject of a compend ms 20-34 for detailed  RECOMMENDATIONS al letter to issue for HFC-130/JAllen HFD-520/Roberts HFD-520/SBRoy:R/D  REVIEWER	phenyl)acetamido] 2.0]-heptane-2-  ene)-7-oxo-4-oxa-1-  RDS AND REPORTS Yes No  Yes No  lial monograph, USP comments.  or this supplement.

- 20. Components and Composition: NA
- 21. Facilities and Personnel: NA
- 22. Synthesis: NA
- 23. Raw Material Controls: NA New Drug Substance
  - Other Ingredients
- 24. Other Firm(s): NA
- 25. Manufacturing and Processing: NA
- 26. Container/Closure: NA
- 27. Packaging and Labeling: NA
- Laboratory Controls (In-process and Finished Dosage 28. Form): NA
- 29. Stability: NA
- 30. Control Numbers: NA
- 31. Samples and Results: NA
  - Validation a.
  - Market Package b.
- 32. Labeling: NA
- 33. Establishment Inspection

On February 2, 1996, the firm withdrew the facility as a source of since it was outside the 2 year compliance period (GMP inspection) and consequently had an impact on the approvability of the NDA application. The facility was inspected on March 14, 1996 and the inspection was satisfactory (report attached - '-

34. Recalls: NA